RESPONSE TO FINDING
IR-00-004-01-FIN

Summary of Finding

Section 5.3.2 of the QAPIP states that processes that affect quality shall be conducted under controlled conditions using approved instructions, procedures, checklists, and other appropriate means. The procedures and instructions shall be prepared at a level of detail appropriate to describe and control the work based on the importance and complexity of the work process being performed.

Contrary to the above, during the inspection procedures associated with self-assessments and quality improvement (for example, K13P054_1, "Corrective Action," and K13P051_2, "Authorization to Stop Work") were found to not be adequate to describe and control the processes necessary to ensure an effective quality improvement program. Examples of these procedural issues are described in Sections 1.2.2 and 1.3.2 of Inspection Report IR-00-004 (enclosure 2).

This is considered an inspection Finding.

BNFL Inc. response:

1. Agreement or disagreement with the Finding

BNFL Inc. agrees with the Finding.

2. Reason for the Finding

Project work was being performed to approved procedures. However, findings by the project and its regulators have found procedures to contain inadequacies and weaknesses. This was a failure by the project to clearly define and implement adequate instructions for the preparation, review, and issuing of procedures leading to inconsistency in the quality of project procedures. Inadequate Quality Assurance (QA) resources for the review of QA department procedures contributed to the problem.

3. Corrective steps that have been taken and the results achieved

Actions taken to date include:

A. Deficiency Report (DR), DR-W375-00-QA00041, Inadequate Procedures Inspection Report IR-00-004-01-FIN, was initiated by Project Quality Assurance on June 5, 2000 to document finding IR-00-004-01-FIN and initiate corrective action.

B. The finding in DR-W375-00-QA00041 describes a condition adverse to quality (CAQ) that was determined to be significant by the QA manager.

C. Based upon this determination, a Corrective Action Report (CAR) CAR-W375-00-QA00016, Self-Assessment and Quality Improvement Procedures IR-00-004-01-FIN, was issued June 7, 2000 to the Project Quality Assurance organization.

D. QA organization staffing has been increased.

Results achieved include:

A. Immediate increase of awareness within the QA organization of the importance of procedural integrity and accuracy.

B. Immediate increase in available QA department human resources to conduct QA activities including QA procedure revisions.

C. Immediate increase in project management awareness of serious deficiencies in QA procedures.

4. The corrective steps that could be taken to avoid further findings

The corrective actions that could be taken include:

A. Full implementation of the new procedure, K13P003, "Production of RPP-WTP Procedures", that addresses the procedure development process to ensure that procedures are written clearly, consistently, and receive the necessary reviews prior to being issued for implementation. The expectation is that this procedure would improve the quality of project procedures.

B. Specific remedial actions that could be taken to correct, clarify, and strengthen procedural deficiencies and/or weaknesses identified in finding IR-00-004-01-FIN include revising the following procedures to implement the changes discussed below:

- K13P054, "Corrective Action"

  There has been a complete revision of the corrective action procedure. The revised procedure was in the final review cycle. The revised procedure addresses:

  1. Providing feedback to the originator following key steps, including validation.
  2. Including the participation of QA in the validation process.
  3. Including steps to ensure that the responsible organization is notified of the condition adverse to quality and provided direction on dispositioning.
  4. Eliminating the requirement for disposition by the QA manager, and redirecting the action to the functional manager.
  5. Including measurable timeframes for completion of key events in the corrective action process to better track rates of progress through the process.
  6. Including provision for requesting approval for changes to corrective action plans, when changes are necessary.
  7. Including the provision for resolution of disagreements between the QA manager and line management.
  8. Including the use of cause codes and risk ranking values to prioritize disposition of conditions adverse to quality.

9. Providing steps to ensure feedback to the originator regarding disposition and closure action.
10. Eliminating the DR and CAR forms by combining them into a single form, "Condition Adverse to Quality Report" (CAQR).
11. The CAQR form would include a signature block for approval of the corrective action plan, which would be required for all conditions adverse to quality.

- K13P051, "Authority to Stop Work"

  Refer to Procedure Change Request (PCR) K13P051A, effective date 6/30/2000 for the changes listed below.

  1. Milestone 1 has been revised to clarify that redlining of work procedures is to be done only in those situations where stoppage of work will result in:
     a. Unacceptable project delay
     b. Where work delay affects product quality
     c. Delay may result in harm to plant assets, personnel, the public, or the environment.
  2. Milestone 1 is correct in the sequencing of events to process a formal change at the time a procedure is redlined. The QA engineer/procedure owner is required to prepare a PCR (see record column) which is then completed by the Responsible Manager.
  3. Milestone 1 third paragraph is to be revised to state: "When a condition adverse to quality is identified, document the condition and initiate corrective action per K13P054, 'Corrective Action' procedure."
  4. Add to the record column for preparation of a Condition Adverse to Quality Report. The revision to K13P054 implements the use of the CAQR. The procedure K13P054, "Corrective Action" is included in the reference section of procedure K13P051.
  5. Revision to procedure K13P051, Milestone 1 clarifies that examples are only for "work stoppage." (Refer to 1 above.)
  6. Milestone 2 is not prescriptive because the actions required of the Responsible Manager may be one or more in a range of actions the QA Manager has the option of requiring.
  7. Milestone 3 was revised to state: "…and concurs with preventive actions to preclude recurrence."

- K13C051, "Code of Practice for RPP-WTP Quality Assurance Program Audits and Assessments"

  Refer to PCR number K13C051A, effective date 6/30/2000 for the changes listed below.

  1. Section 8.0, Paragraph I is revised to read:

     "Conditions adverse to quality identified during the performance of an external audit shall be documented by the auditor on a Condition Adverse to Quality Report (CAQR)

form and corrected by the audited organization during the audit when possible. If the condition is corrected during the audit, the CAQR form will be used to document the corrective actions taken and the concurrence of the Lead Auditor that the actions satisfy program requirements. If the condition identified cannot be corrected during the audit, the CAQR form will be entered into the Corrective Action Management System per procedure K13P054, 'Corrective Action'."

- K10P008, "Management Assessments"

  The "Management Assessment" procedure could be revised to include the following changes:

  1. Include a requirement for the direct participation of the manager in the performance of the assessment.
  2. Include the requirement for establishing review guidance for each assessment element.
  3. The evaluation/validation process is located in the "Corrective Action" procedure, K13P054. The "Management Assessment" procedure should reference the "Corrective Action" procedure for the processing of potential conditions adverse to quality.
  4. The scheduling of management assessments could be accomplished by development and revision of the Annual Management Assessment Plan, which is part of the Project Management Plan/Project Execution Plan. This approach would provide a standardized method of scheduling management assessments, add visibility to the schedule, and provide the ability to provide performance and completion metrics.
  5. The requirement for assessment of corrective action effectiveness is to be located in the "Corrective Action" procedure, K13P054. Including this requirement in the "Management Assessment" procedure would be redundant. The "Management Assessment" procedure should make reference to the "Corrective Action" procedure for followup assessments to measure effectiveness.

- K13P061, "Root Cause Analysis"

  The "Root Cause Analysis" (RCA) procedure was rewritten and was in the final review cycle. The procedure rewrite addresses the following:

  1. The requirements for performing a root cause analysis have been defined in K13P061, Sections 2.0 and 3.2.2.a. The procedure, K13P054, "Corrective Action" also defines the requirement for performing a RCA for significant conditions adverse to quality.
  2. K13P054, Corrective Action", establishes timeframes (schedule) for the timely completion of a RCA.
  3. K13P061, Section 3.2.2.b defines the resource requirements for performance of a RCA.
  4. Procedure K13P059, "PAAA Compliance and Reporting", Sections 3.1, third paragraph and 3.2.3 address reporting requirements that may originate from the performance of a RCA.

5. K13P061, Section 3.3 requires the manager of the affected organization or designee to evaluate the RCA final report and resolve identified deficiencies.
6. K13P061, Section 3.3 and Appendix C describe the process for performance of a RCA.
7. K13P061, Section 3.2.3 requires the RCA Team leader to coordinate the writing of the RCA report. This section was revised to add: "The RCA report shall be written using the project approved Technical Report format."
8. The rewrite of K13P061 in accordance with procedure K13P003, "Production of RPP-WTP Procedures" is expected to eliminate discrepancies between the flow chart and procedure text.

- K13P055, "Corrective Action Management System"

  Reference PCR number K13P055B, effective date 6/30/2000 for the changes listed below.

  1. The following revisions have been made to the procedure to clarify the roles and responsibilities of the QA Manager.
     a. Milestone 1 was changed to state:

        "Jointly with the Project Manager, identifies trends and takes actions to investigate trends."

     b. The flowchart was modified to reflect these milestone changes.
     c. No change is needed to address the disposition of significant Deficiency Reports and Corrective Action Reports. This disposition is addressed in the suggested revision to procedure K13P054, "Corrective Action".

- K13P056, "Identification of Nonconforming Conditions"

  1. A revision to procedure K13P056 was issued to correct the errors in references to appendices. Refer to PCR number K13P056A, dated 6/2/2000. The changes made were:
     a. Appendix 4 changed to Appendix 3
     b. Appendix 5 changed to Appendix 4
     c. Appendix 6 changed to Appendix 5
  2. Reference PCR number K13P056B, effective date 6/30/2000 for the changes listed below:
     a. Appendix 1, Item 2 is changed to read:

        "The originator's supervisor shall perform an initial review to concur with the description of the nonconforming condition. The supervisor will also validate that the condition is the proper subject of an NCR. The supervisor will notify the originator of the decision. If the supervisor does not agree that the NCR should be submitted, and the originator does not agree with the decision, the issue shall be raised to successive levels of management until resolved, or the originator may submit the

issue to the Employee Concerns Program (ECP) per K21C001, 'Code of Practice for Employees Concern Program.' "

This change will ensure that the originators receive feedback from their supervisors and have a method for resolving disagreements.

b. The Nonconformance Report form, K13F056, was revised by adding a check-off block for indicating "rework" in the space for recording of technical justification.

Appendix 3 (directions for completing the form), Item (8) states that the technical justification space is to be used to provide a detailed disposition. It is expected that a disposition description would include a description of any rework actions.

c. Appendix 3, Item (7) has been revised to read: "The QA Manager indicates whether the NCR represents a significant condition adverse to quality to be processed in accordance with procedure K13P054, 'Corrective Action' ".

This change removes the reference to 2.2 previously found in this item.

d. Appendix 3, Item (8) has been revised to read: "The detailed disposition is to be provided by the designated engineer and will include sufficient technical justification and inspection/test requirements. The inspection/test requirements shall include any QA/QC specified inspections/tests."

This change will ensure input from QA/QC is sought for inspection/test requirements.

The QA Manager would sign and date the NCR form to indicate that the disposition satisfies the Quality Assurance Program requirements, including any applicable inspections/tests.

e. Appendix 3, Item 13 has been revised: the words "Action Party" have been replaced with "personnel responsible for the action".

f. Appendix 3, Item 14 has been revised: the words "The Action Party" have been replaced with "The personnel responsible for the action".

g. The form K13F056, item 13 has been revised: the words "Action Party" have been replaced with "Personnel Responsible".

- K13P059, "Identification, Tracking, and Reporting of Price Anderson Amendment Act Noncompliance"

K13P059 was rewritten and was in the review cycle. It was renamed to "PAAA Compliance and Reporting". Enhancements to the procedure include:

1. Addition of detailed forms
2. Addition of instructions for Price Anderson Amendment Act (PAAA) screening
3. Clarification of assignment of responsibilities
4. Section 3.3.1, Step 8 was revised to read:

"If the Project Manager does approve a decision to make a NTS report, the PAAA Coordinator, shall prepare a draft NTS report and should obtain review by the QA

Manager, counsel, and the Project Manager. After resolution of comments, the Project QA Manager should concur and the Project Manager shall approve the draft NTS report. The PAAA Coordinator shall enter the report into the DOE NTS System and should interface with the CAMSD Coordinator to update the CAMS database."

- K13P062, "Quality Trending"

  Reference PCR number K13P062B, effective date 6/30/2000 for the changes listed below:

  1. Milestone 2 was changed to read:

     "The CAMS data is sorted by specific fields and compiled in charts, tables and graphs for use in the analysis for adverse trends. The Project QA Manager and CAMS Database Coordinator review the data to determine if adverse trends exist. If a trend is identified and determined to be significant by the Project QA Manager, it is to be reported to project management per procedure K13P054, "Corrective Action".

  2. The flowchart was revised to reflect this change. Changes to procedure K13P054, "Corrective Action" will require additional changes to the flowchart.

5. The date when full compliance with the applicable commitments in the authorization basis will be achieved

Due to termination of the contract between BNFL Inc. and the Department of Energy, no dates are cited for future actions to achieve full compliance with the authorization basis.

A. The following procedures were revised and issued with the effective date 6/30/2000:

   K13P051, "Authority to Stop Work"

   K13C051, "Code of Practice for RPP-WTP Quality Assurance Audits and Assessments"

   K13P055, "Corrective Action Management System"

   K13P056, "Identification of Nonconforming Conditions" (also revised with the effective date 6/2/2000)

   K13P062, "Quality Trending"

B. The following procedures need to be revised:

   K13P054, "Corrective Action"

   K10P008, "Management Assessment"

   K13P061, "Root Cause Analysis"

   K13P059, "PAAA Compliance and Reporting"

C. Training or retraining requirements should be identified in accordance with the procedure change process and documented on the PCR form at the time the procedure revisions are submitted to Project Document Control for issue. As a minimum, training should be given to project QA staff and employees and managers in other departments responsible for the QA functions covered by the above procedures.

D. The schedule for completion of the training or retraining required should be in accordance with requirements established in the project training and development plan.

RESPONSE TO FINDING
IR-00-004-02-FIN

Summary of Finding

Section 3.2.2 of the QAPIP requires conditions adverse to quality to be managed to disposition and closure of the identified conditions are to be performed in a timely manner.

Contrary to the above, during the inspection 12 examples of failure to address deficiencies in a timely manner were identified (for example, DR-W375-99-QA00059 was issued June 9, 1999, concerning problems with quality improvement procedures; however, the procedures had not been revised to reflect the recommended disposition of the DR at the time of the inspection [May 1, 2000]). This and other examples are described in Sections 1.5.2 and 1.7.3 of Inspection Report IR-00-004 (Enclosure 2).

This is considered an inspection Finding

- *DR-W375-99-QA00059: This DR identified a large number of problems with quality improvement procedures. The DR was written June 9, 1999, and remained open at the time of the inspection. QAPIP Section 3.2.2 requires conditions adverse to quality to be managed to disposition and closure of the identified conditions are to be performed in a timely manner. Although the Contractor had specified a number of changes to procedures to address the problems, implementation had not been timely. Failure to address this deficiency in a timely manner is considered an example of a Finding (IR-00-004-02a-FIN).*
- *DR-W375-99-QA00065: This DR identified that contrary to ISMP Section 3.9.1.2, the Contractor had not prepared a set of radiation protection drawings that showed the facility zoning and minimum shielding requirements and access control features. The DR was written on July 2, 1999. The initial disposition indicated that a change to the ISMP would be generated to reflect the Contractor's practice of having standard project drawings (e.g., project flow diagrams, piping and instrument drawings, and layout drawings) show as low as is reasonable achievable (ALARA) features such as zoning, shielding, and access control provisions. However, as of the time of the inspection, the Contractor had not processed the ISMP change to reflect the above disposition. Failure to address this deficiency in a timely manner is considered an example of a Finding (IR-00-004-02b-FIN).*
- *DR-W375-99-QA00071: This DR identified that new laws, regulations, and guidance documents were not being evaluated by the project for applicability to project programs. The DR was issued on July 22, 1999, and was still open at the time of the inspection. The DR was characterized as non-significant. ISMP Section 2.1 states that new laws, regulations, and guidance documents are reviewed for applicability to the project. In a response memorandum to QA, dated March 23, 2000, eight months after the DR was issued, it stated that a formal program addressing this requirement did not exist, although it was also stated that ad hoc reviews were done. A plan for formalizing the process was also discussed in the response with the development of the procedure due by April 21, 2000. As of the time of the inspection a draft procedure had been developed and was being circulated for concurrence. Failure to respond to this DR in a timely manner is considered an example of a Finding (IR-00-004-02c-FIN).*
- *DR-W375-99-QA00072 and CAR-W375-99-QA00031: This DR and CAR identified that a number of DR and CAR records were missing from Project Document Control (PDC). The DR had been written on July 28, 1999, and the CAR had been written on July 29, 1999. The Contractor had performed an assessment of the problem and had written a summary of the causes and proposed actions to address the*

problems. However, corrective actions, which included providing PDC with the missing records and revising K13P054 to specify more clearly the requirement to route the documents to PDC for records storage, had not been completed at the time of the inspection. Failure to address this deficiency in a timely manner is considered an example of a Finding (IR-00-004-02d-FIN).

- *DR-W375-99-QA00082: This DR identified that the standard selection process was not being fully implemented as documented in the SRD and project implementing procedures. The DR was issued on August 27, 1999, and was characterized in the CAMS database as not significant and overdue. The initial response, which was also the closeout response to this item, was dated April 10, 2000, almost eight months after the item was issued. The item was closed based upon the ISM cycle 1 & 2 processes. Failure to respond to this DR in a timely manner is considered an example of a Finding (IR-00-004-02e-FIN).*
- *DR-W375-99-QA00087 and CAR-W375-99-QA00036: The DR and CAR were written on October 18, 1999, and October 20, 1999, respectively. These documents identified that QA had not performed internal audits per the project schedule nor had they updated the schedule to reflect the current auditing status. The schedules were not updated until February 15, 2000, and the CAR was not closed until April 18, 2000. Failure to address this deficiency in a timely manner is considered an example of a Finding (IR-00-004-02f-FIN).*
- *DR-W375-99-QA00095: The DR resulted from QA surveillance activities associated with the review of thirty-eight calculations. The DR identified that authorization basis (AB) screenings had not been performed. The QA surveillance auditor interviewed engineering staff including the calculation originators, and none had a good explanation for why AB screenings had not been done. The DR was issued on November 3, 1999, was classified as significant, and was still open. No correspondence occurred on this DR between November 3, 1999 and February 16, 2000. On March 15, 2000, actions to address the DR was extended to April 21, 2000. As of April 25, an initial response had not occurred. Based on the request by QA in the cover letter that transmitted the DR to the responsible organization, the initial response should have been completed within 30 days of November 3, 1999. Failure to respond to this DR in a timely manner is considered an example of a Finding (IR-00-004-02g-FIN).*
- *DR-W375-99-QA00097: The DR identified that training requirements were not being met for the AB process. People were originating documents without understanding procedures or attending the required AB training. Thirty of fifty-six originators did not attend the November 1998 training. This item was issued on November 3, 1999, and remained open. At the time of the inspection, the initial response had not been generated. Document review indicated that the initial response due date was moved out to April 28, 2000. Failure to respond to this DR in a timely manner is considered an example of a Finding (IR-00-004-02h-FIN).*
- *DR-W375-00-QA00020: The Contractor performed QA surveillance, SV-W375-00-QA00007, of actions taken on documents where Document Control identified errors in processing. The surveillance report was issued on March 21, 2000. Document Control had identified errors in 276 documents. Of these, the QA surveillance identified 52 where changes were made to them prior to them being sent to Document Control. Of the 52, only 29% were properly processed in the originating department. This DR was issued on April 25, 2000, apparently in response to the inspector's inquiry. Failure to address this deficiency in a timely manner is considered an example of a Finding (IR-00-004-02i-FIN).*
- *DR-W375-99-QA00049 Rev.1: This DR concerned failure to record all objectives and findings during the performance of design reviews. The DR was written on May 14, 1999, but the disposition was not*

issued until March 7, 2000. Failure to address this deficiency in a timely manner is considered an example of a Finding (IR-00-004-02j-FIN).

- *DR-W375-99-QA00083: This DR indicated that the standard selection process was not fully implemented as documented in the SRD. This DR was opened on August 27, 1999, and was indicated as closed in the CAMS database. Upon review of the file supporting this DR, no information supporting closure was identified. The CAMS database was supposed to be a summary of what was in the DR file. The Contractor had no explanation for the inconsistency between the DR file and the CAMS database and stated that the item was not complete and that the CAMS database would be changed to indicate the item was still open. Failure to address this deficiency in a timely manner is considered an example of a Finding (IR-00-004-02k-FIN).*
- *IR-99-003-02-FIN, "The Contractor had not established or implemented methods for using performance indicators to determine the frequency of independent assessments." […]*

  The inspectors also found that a requirement for using performance indicators as input for determining frequency of independent assessment was included in revisions to K13C051_1, "Code of Practice for RPP-WTP Quality Assurance Program Audits and Assessments," dated 03/00, and K13P053A_1, Quality Assurance Surveillance, dated 03/00. Training records provided evidence that QA staff were trained on the need to use performance indicators to determine the frequency of independent assessments.

  Although the procedures were adequately revised to address the identified problems, the Contractor had committed to revise the procedures by September 30, 1999. Failure to revise the procedures until March 2000, is an example of a Finding regarding untimely corrective action (IR-00-004-02l-FIN).

BNFL Inc. response:

1. Agreement or disagreement with the Finding

BNFL Inc. agrees with the Finding

2. Reason for the Finding

The failure in processing corrective actions in a timely manner occurred for the following reasons:

A. An effective method of preparing, executing, reviewing, and closing corrective actions was not adequately implemented.

B. Inadequate QA resources were provided.

C. Corrective action work was not given a high priority.

D. There were unclear management expectations.

3. Corrective steps that have been taken and the results achieved

The following corrective steps have been taken:

A. Deficiency Report DR-W375-00-QA00043, Failure to Address Deficiencies in a Timely Manner IR-00-004-02-FIN, was initiated by Project Quality Assurance to document corrective actions

regarding the condition adverse to quality that is the failure to implement an adequate corrective action management program.

B. QA points of contact were designated and assigned responsibility for tracking to closure all open corrective actions. The points of contact worked with responsible management to assure that progress was being made in addressing the open corrective actions. The QA Corrective Action Management System database administrator provided weekly status reports to each point of contact to assure visibility was maintained on each open corrective action.

C. The past practice of reporting open corrective actions at the monthly Project Managers meeting by the QA Manager was augmented by the implementation of the point of contact concept and the issuing of an "advance warning" status report to each responsible manager two weeks prior to the monthly Project Managers meeting. This "advance warning" status report provided added visibility of open corrective actions to the responsible manager.

The results achieved from the actions described above include a noticeable improvement in the timeliness of closure of corrective actions as evidenced in the attached metric "Corrective Action Management System Cumulative Totals" for the period from November 1998 through June 2000. Eight of the twelve examples cited in finding IR-00-004-02-FIN are now closed.

4. The corrective steps that could be taken to avoid further Findings

Completion, revision, and implementation of procedure K13P054, "Corrective Action". This would implement time limits between key process steps. Additional date fields were to be added to the CAMS database to provide the ability to track performance to these time limits. Metrics were being developed to provide management with reports on performance against corrective action process goals. These reports would provide management the ability to monitor timeliness of closure, identify delinquencies, and initiate appropriate actions when needed.

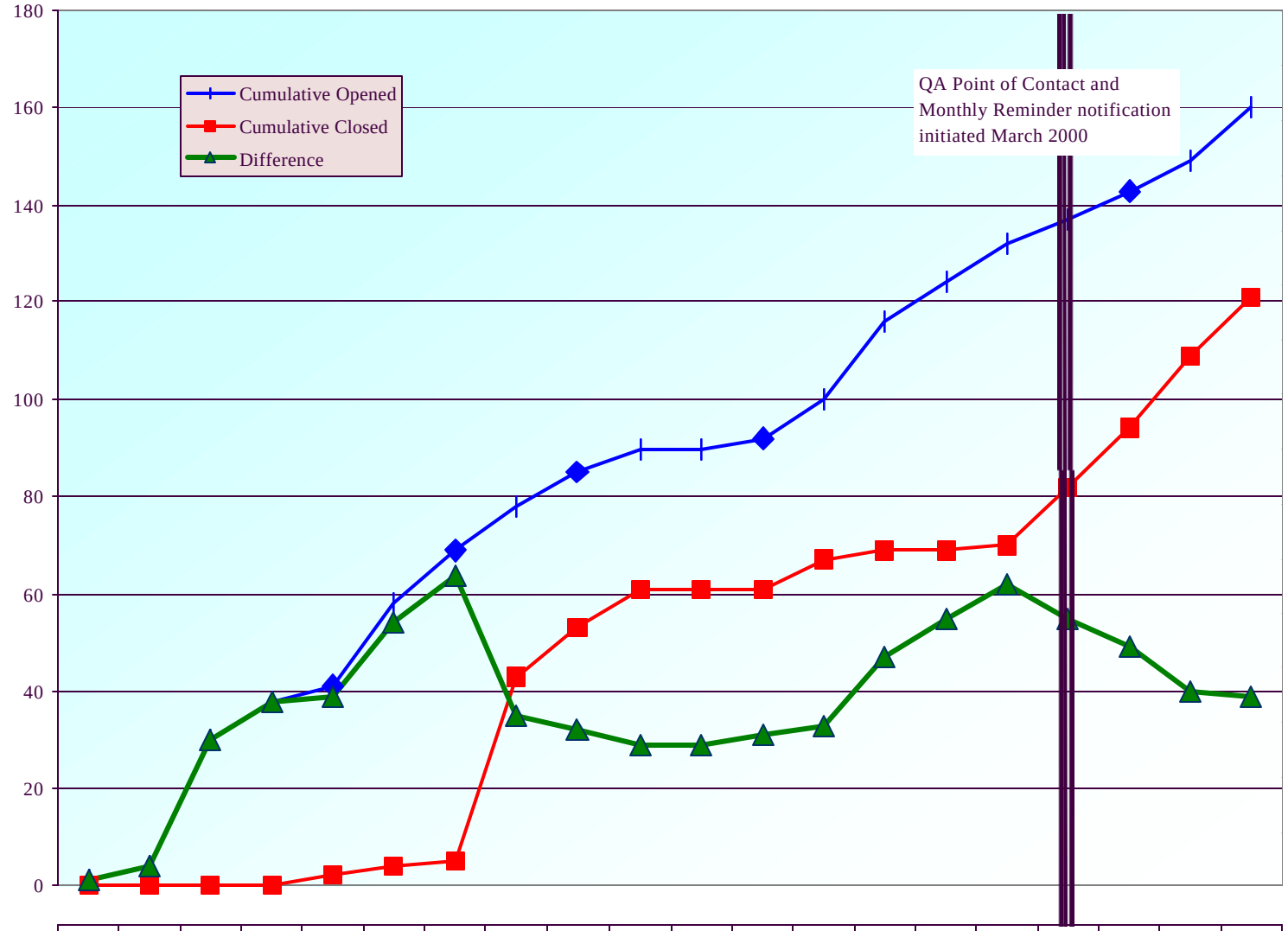
5. The date when full compliance with the applicable commitments in the authorization basis will be achieved

Due to termination of the contract between BNFL Inc. and the Department of Energy, no dates are cited for future actions to achieve full compliance with the authorization basis.

The following procedure needs to be revised:

K13P054, "Corrective Action"

b l Corrective Action Management System Cumulative Totals



	Nov-98	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00
Cumulative Opened	1	4	30	38	41	58	69	78	85	90	90	92	100	116	124	132	137	143	149	160
Cumulative Closed	0	0	0	0	2	4	5	43	53	61	61	61	67	69	69	70	82	94	109	121
Difference	1	4	30	38	39	54	64	35	32	29	29	31	33	47	55	62	55	49	40	39

RESPONSE TO FINDING
IR-00-004-03a-FIN

Summary of Finding

Section 5.3.2, "Instructions and Procedures," of the QAPIP requires processes that affect quality to be conducted using approved instructions and procedures.

a. Procedure K13P054_1, "Corrective Actions," Milestone 3, required the QA Manager to initiate Corrective Action Reports (CARs) for conditions adverse to quality the are considered to be significant.

Contrary to the above, DR-W375-99-QA00095 was issued on November 3, 1999, and was designated as significant. However, as of April 21, 2000, the QA manager had failed to issue the required CAR.

The [three] issues described above are considered examples of a Finding regarding failure to follow procedures.

BNFL Inc. response:

1. Agreement or disagreement with the Finding

BNFL agrees with the Finding.

2. Reason for the Finding

The surveillance from which DR-W375-99-QA00095, Under Surveillance of Authorization Basis Maintenance, originated (SV-W375-99-QA00016, Surveillance of Authorization Basis Maintenance) resulted in a total of seven Deficiency Reports (DRs), six of which were significant. It was the intent of Quality Assurance (QA) to review these six DRs and combine them into a smaller number of Corrective Action Reports (CARs). The Audit and Surveillance Lead had not consolidated the six DRs into a smaller number of CARs to complete the actions. This issue relates to the timeliness of the corrective action in addition to the failure to follow procedures. This did not happen due to inadequate resources within the QA Organization, prioritization of QA resources, and unclear management expectations.

3. Corrective steps that have been taken and the results achieved

The corrective steps that have been taken include:

A. Deficiency Report DR-W375-00-QA00044, Failure to Follow Procedures IR-00-004-03-FIN, was initiated by QA on June 16, 2000 to document and initiate corrective action regarding the condition sited in IR-00-004-03-FIN, Issue a.

B. The finding in DR-W375-00-QA00044 described a condition adverse to quality (CAQ) that was determined to be significant by the QA manager.

C. Based upon this significance determination, a Corrective Action Report CAR-W375-00-QA00018, Corrective Actions – IR-00-004-04-FIN, was issued June 20, 2000 to the project Quality Assurance organization.

D. The Quality Assurance organization staffing levels were augmented for the express purpose of redistributing the workload within QA. Since November 1999 when SV-W375-99-QA00016, Surveillance of Authorization Basis Maintenance, was performed, eight individuals were added to the organization.

E. A post-facto review was performed on the subject DRs for potential stop work issues. The review indicated that none of the deficiencies would have resulted in a stop work order. This review is documented in memorandum CCN 104036, dated June 15, 2000.

F. The seven DRs from SV-W375-99-QA00016, Surveillance of Authorization Basis Maintenance, have been closed. Because these deficiencies closely mirrored findings from the RU inspection report IR-99-007 on Authorization Basis Maintenance, they were addressed in tandem with, and at the same level of rigor as, the RU findings. The findings were handled as significant conditions adverse to quality.

The results achieved include:

A. DR-W375-00-QA00044, Failure to Follow Procedures IR-00-004-03-FIN, and CAR-W375-00-QA00018, Corrective Actions – IR-00-004-03-FIN, remain open pending submittal and Regulatory Unit acceptance of the response to inspection report IR-00-004, and completion of the corrective actions associated with finding IR-00-004-03-FIN.

B. The staff augmentation in the QA organization led to improved quality in the work produced by the QA organization.

C. The findings associated with the Authorization Basis Maintenance inspection are either closed or pending internal verification with the exception of IR-99-001-01-FIN (failure to establish a process that would ensure the authorization basis was maintained current with respect to the facility design) which remains open pending a QA surveillance of the authorization basis maintenance process.

4. The corrective steps that could be taken to avoid further Findings

The corrective steps that could be taken include:

A. Provide adequate QA personnel to ensure sufficient resources are available for the QA department to accomplish its mission.

B. Continued increase in management awareness and sensitivity to the recent set of RU findings against the QA program. Clear management direction on program corrective actions. Assignment of the highest priority to corrective action work.

C. Complete procedural improvements that were underway. The revision of the “Corrective Action” procedure, K13P054, would eliminate the use of a separate CAR form. The intent is to have a single form for documenting all conditions adverse to quality (CAQ). All CAQs would continue to be screened for significance. When a CAQ is identified as being significant, it would be identified on the form and elevated to a greater level of rigor in processing than those determined to be non-significant. This change would eliminate the potential for situations such as the one documented in IR-00-004-03-FIN, Issue a.

D. Once the “Corrective Action” procedure is issued for project use, training would be provided to QA and other project personnel on the revised procedure.

5. The date when full compliance with the applicable commitments in the authorization basis will be achieved

Due to termination of the contract between BNFL Inc. and the Department of Energy, no dates are cited for future actions to achieve full compliance with the authorization basis.

A. K13P054, “Corrective Action” needs to be revised.

B. Training of QA personnel and other project personnel to the revised procedure would be identified per the procedure change process and documented on the Procedure Change Request form at the time the procedure is submitted to Project Document Control for issue.

C. The schedule for completion of the training or retraining would be in accordance with requirements established by the project training and development plan.

RESPONSE TO FINDING
IR-00-004-03b-FIN

Summary of Finding

Section 5.3.2, "Instructions and Procedures," of the QAPIP requires processes that affect quality to be conducted using approved instructions and procedures.

b. Procedure K13C054_1, [K13P054_1] "Corrective Action," required deficiency reports (DRs) to be written to identify and correct discrepancies associated with documents.

Contrary to the above, surveillance SV-W375-00-QA0007 was completed March 17, 2000, and identified numerous errors regarding the manner in which changes were made to documents, however, as of April 21, 2000, no DRs had been generated to reflect the deficiencies.

The [three] issues described above are considered examples of a Finding regarding failure to follow procedures.

BNFL Inc. response:

1. Agreement or disagreement with the Finding

BNFL agrees with the Finding.

2. Reason for the Finding

Although the pen and ink changes to documents noted in surveillance SV-W375-00-QA00007, Document Correction Practices, may have been minor incidents, the process issue was significant. The absence of the General Manager from the site, whose signature was required, caused a delay in the issuance of the Deficiency Report.

3. Corrective steps that have been taken and the results achieved

The corrective steps that have been taken include:

A. Deficiency report DR-W375-00-QA00044, Failure to Follow Procedures IR-00-004-03-FIN, was initiated by project QA on June 16, 2000 to document and initiate corrective actions regarding the condition cited in IR-00-004-03-FIN, Issue b.

B. The finding in the DR described a condition adverse to quality (CAQ) that was determined to be significant by the QA Manager.

C. Based upon the significance determination, a Corrective Action Report CAR-W375-00-QA00018, Corrective Actions – IR-00-004-04- FIN, was issued on June 20, 2000 to the project Quality Assurance organization.

D. DR-W375-00-QA00020, Document Correction Practice, was signed and delivered to Project Document Control on April 25, 2000.

The results achieved include:

A. DR-W375-00-QA00044, Failure to Follow Procedures IR-00-004-03-FIN, and CAR-W375-00-QA00018, Corrective Actions – IR-00-004-03-FIN, remain open pending submittal and Regulatory Unit acceptance of the response to inspection report IR-00-004, and completion of the corrective actions associated with finding IR-00-004-03-FIN.

B. DR-W375-00-QA00020, Document Correction Practice, was closed on June 1, 2000.

4. The corrective steps that could be taken to avoid further Findings

The corrective steps that could be taken include:

A. Provide additional QA personnel to ensure adequate resources are available for the QA department to accomplish its mission.

B. Continued increase in management awareness and sensitivity to the recent set of RU findings against the QA program. Clear management direction on program corrective actions. Assignment of the highest priority to corrective action work.

C. Procedural improvements were underway. The revision of the "Corrective Action" procedure, K13P054 would provide greater administrative direction in the generation of CAQRs. The revision would involve the manager of the organization of primary responsibility in the process from the beginning. This change would assure more rapid issuance of CAQRs and eliminate the potential for further situations such as the one documented in IR-00-004-03-FIN, Issue b.

D. Once the Corrective Action Procedure is issued for project use, training would be provided to QA and other project personnel on the revised procedure.

5. The date when full compliance with the applicable commitments in the authorization basis will be achieved

Due to termination of the contract between BNFL Inc. and the Department of Energy, no dates are cited for future actions to achieve full compliance with the authorization basis.

A. K13P054, "Corrective Action" needs to be revised.

B. Training of QA personnel and other project personnel to the revised procedure would be identified per the procedure change process and documented on the Procedure Change Request form at the time the procedure is submitted to Project Document Control for issue.

C. The schedule for completion of the training or retraining required would be in accordance with requirements established by the project training and development plan.

RESPONSE TO FINDING
IR-00-004-03c-FIN

Summary of Finding

Section 5.3.2, "Instructions and Procedures," of the QAPIP requires processes that affect quality to be conducted using approved instructions and procedures.

c. Procedure K13C054_1, [K13P054_1] required conditions adverse to quality to be documented in deficiency reports.

Contrary to the above, as of April 21, 2000, RU Inspection Finding IR-99-007-01-FIN, issued on December 13, 1999, had not been documented in a deficiency report. In addition, other issues identified by outside entities (for example, other RU inspection Findings and Office of River Protection Deviation and Corrective Action Reports) were not being documented in deficiency reports.

The [three] issues described above are considered examples of a Finding regarding failure to follow procedures.

BNFL Inc. response:

1. Agreement or disagreement with the Finding

BNFL partially agrees with the Finding.

The requirement to document deficiencies on a deficiency report in procedure K13P054, “Corrective Action”, is directed at project personnel. As the inspection and surveillance findings by other organizations are documented by a method of the other organization, it could be stated that the requirement is on the originating organization to complete the deficiency report as required by K13P054.

As stated in finding IR-00-004-03c-FIN, if the expectation is that after the project agrees with the finding, a deficiency report is written by the agreeing organization, then a double identification system has been established. The Corrective Action Management System (CAMS) under procedures K13P054, “Corrective Action”, and K13P055, “Corrective Action Management System”, has consistently provided the same level of identification, tracking, and monitoring of internally and externally identified deficiencies. The major issue in the process is the determination of significance and other required actions (e.g., PAAA screening, Employee Concerns, health and safety issues) applicable to the project. This issue is a result of the intent of the project to treat externally identified conditions adverse to quality in the same manner as internally identified conditions but not to process duplicate paperwork.

2. Reason for the Finding

At that time, BNFL Inc. elected not to initiate a Deficiency Report (DR), because database tracking capability had improved. Instead, finding IR-99-007-01-FIN was entered directly into the CAMS database for tracking and resolution.

3. Corrective steps that have been taken and the results achieved

The corrective steps that have been taken include:

A. Deficiency Report DR-W375-00-QA00044, Failure to Follow Procedures IR-00-004-03-FIN, was initiated by project Quality Assurance on June 16, 2000 to document and initiate effective corrective action regarding the condition cited in IR-00-004-03-FIN, Issue c.

B. The finding in DR-W375-00-QA00044 described a condition Adverse to quality (CAQ) that was determined to be significant by the QA Manager.

C. Based upon the significance determination, a Corrective Action Report CAR-W375-00-QA00018, Corrective Actions – IR-00-004-04- FIN, was issued on June 20, 2000 to the project Quality Assurance organization.

D. The CAMS database practice was modified to assure that all conditions adverse to quality are automatically provided to the Price Anderson Amendment Act Coordinator for review in accordance with procedure K13P059, "Identification, Tracking, and Reporting of Price Anderson Amendment Act Noncompliance", to determine if there is a basis for submitting a Noncompliance Tracking System (NTS) report.

The results achieved include:

A. DR-W375-00-QA00044, Failure to Follow Procedures IR-00-004-03-FIN, and CAR-W375-00-QA00018, Corrective Actions – IR-00-004-03-FIN, remain open pending submittal and Regulatory Unit acceptance of the response to inspection report IR-00-004, and completion of the corrective actions associated with finding IR-00-004-03-FIN.

B. All deficiencies currently entered in the CAMS system have been screened for compliance with the requirements of the Price Anderson Amendment Act.

4. The corrective steps that could be taken to avoid further Findings

The corrective steps that could be taken include:

A. Provide additional QA personnel to ensure adequate resources are available for the QA department to accomplish its mission.

B. Continued increase in management awareness and sensitivity to the recent set of RU findings against the QA program. Clear management direction on program corrective actions. Assignment of the highest priority to corrective action work.

C. Procedural improvements were underway. K13P054, "Corrective Action" was being revised to assure that externally identified CAQs are identified, tracked, and completed by the project in the same or similar manner as CAQs identified internally.

D. Once the "Corrective Action" procedure is issued for project use, training would be provided to QA and other project personnel on the revised procedure.

5. The date when full compliance with the applicable commitments in the authorization basis will be achieved

Due to termination of the contract between BNFL Inc. and the Department of Energy, no dates are cited for future actions to achieve full compliance with the authorization basis.

A. K13P054, “Corrective Action” needs to be revised.

B. Training of QA personnel and other project personnel to the revised procedure would be identified per the procedure change process and documented on the Procedure Change Request form at the time the procedure is submitted to Project Document Control for issue.

C. The schedule for completion of the training or retraining required would be in accordance with requirements established by the project training and development plan.